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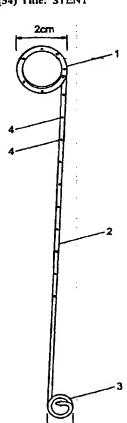
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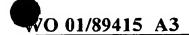
[Continued on next page]

(54) Title: STENT



(57) Abstract: There is provided an indwelling ureteral (ureteric) stent comprised of a hollow flexible tube with an upper end section, a substantially straight middle section and a lower end section. The upper and lower sections are preferably coiled. The coiled upper section has a diameter between 1 and 2.5 cm which retains the upper section of the stent in the kidney, and has perforations in the surface to allow drainage of urine from the kidney into the tube. The lower coiled section of the stent is G-shaped. The tip of this lower section assumes the horizontal portion of the G shape and contains an integral valve. The integral valve maintains an open flow of urine from the kidney to the bladder, but prevents the reflux of urine into the kidney during bladder contraction. The stent further comprises a small cuff or series of studs behind said valve against which a stent pusher may rest.

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B. FIELDS SEARCHED

 $\begin{array}{ll} \mbox{Minimum documentation searched (classification system followed by classification symbols)} \\ \mbox{IPC 7} & \mbox{A61F} & \mbox{A61M} \end{array}$

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

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Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	page 9, line 22 -page 10, line 24; figures page 5, line 10 -page 6, line 6	4,5,7,8
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Further documents are listed in the continuation of box C.	X Patent family members are tisted in annex.
Special categories of cited documents: A document defining the general state of the an which is not considered to be of particular relevance E earlier document but published on or after the international	*T* tater document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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O document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed	ments, such combination being obvious to a person skilled in the art. *&* document member of the same patent family
Date of the actual completion of the international search	Date of mailing of the international search report
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Name and mailing address of the ISA	Authorized officer
European Patent Office. P.B. 5818 Patentlaan 2 NL → 2280 HV Rÿswÿk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl. Fax: (+31-70) 340-3016	Kousouretas, I

INTER ONAL SEARCH REPORT

Internal Application No PC1/GB 01/02323

		C17GB 01/02323
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alegory *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 354 263 A (COLL MILTON E) 11 October 1994 (1994-10-11)	10-12
Α	column 3, line 60 -column 6, line 3; figures	4,13,14, 16-21
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	:	

ational application No. PCT/GB 01/02323

INTERNATIONAL SEARCH REPORT

Box I	Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)
This Inter	mational Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1.	Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
· · · ·	Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3.	Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box II	Observations where unity of invention is lacking (Continuation of item 2 of first sheet)
This Inter	national Searching Authority found multiple Inventions in this international application, as follows:
	see additional sheet
1. X	: As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.	As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.	As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.	No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark	on Protest The additional search lees were accompanied by the applicant's protest.
	No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-3

An indwelling ureteral stent comprising an elongated tubular body, an upper end section, a straight middle section and a lower end section wherein the tip of the lower end section of the stent comprises a valve as an integral part of the flexible material comprising the stent.

2. Claims: 4-9

An indwelling ureteral stent comprising an elongated tubular body, an upper end section, a straight middle section and a lower end section wherein the upper lower section forms a closed loop such that the tip of the end section of the stent is not exposed.

3. Claims: 10-12

An indwelling ureteral stent comprising an elongated tubular body, an upper end section, a straight middle section and a lower end section wherein the flexible material decreases in external diameter from the upper end section to the lower end section.

4. Claims: 13-22

An indwelling ureteral stent comprising an elongated tubular body, an upper end section, a straight middle section and a lower end section wherein the stent further comprises at least one projection against which a stent pusher may rest.

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PCT/GB 01/02323

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(54) Title: STENT

(57) Abstract: There is provided an indwelling ureteral (ureteric) stent comprised of a hollow flexible tube with an upper end section, a substantially straight middle section and a lower end section. The upper and lower sections are preferably coiled. The coiled upper section has a diameter between 1 and 2.5 cm which retains the upper section of the stent in the kidney, and has perforations in the surface to allow drainage of urine from the kidney into the tube. The lower coiled section of the stent is G-shaped. The tip of this lower section assumes the horizontal portion of the G shape and contains an integral valve. The integral valve maintains an open flow of urine from the kidney to the bladder, but prevents the reflux of urine into the kidney during bladder contraction. The stent further comprises a small cuff or series of studs behind said valve against which a stent pusher may rest.

1

STENT

3	The present invention relates to an indwelling
4	ureteral (ureteric) stent which exhibits improved
5	anti-reflux properties and which also reduces
6	bladder irritation.
7	
8	Ureteral stents are used in endo-urological
9 .	intervention on a daily basis to allow drainage of
10	urine from the kidneys to the bladder in instances
11	of actual or potential ureteral obstruction. Such
12	instances include ureteral injury due to trauma,
13	obstructive uropathy such as kidney stones, and
14	following surgery in the upper or lower urinary
15	tracts.
16	
17 :	Generally, stents are comprised of a hollow tube
18	made of flexible material, of length varying from
19	25-35cm with an external diameter from about 1.5-3mm
20	and an internal diameter of about 0.5-2mm. Both
21	ends are curled, forming spirals which produce an
22	'O'shape at each end of the stent. This allows the

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upper end to be retained within the kidney and the 1 2 lower end within the bladder, thus preventing movement after placement. The flexibility of the 3 comprising material allows the stent to conform to any curves of the ureter and also allows placement 5 and removal through narrow urological instruments 6 placed by means of the urethra. Currently the 7 commonest form of stent used is known as a Double J . 8 Stent, or Double Pigtail Stent. 9 10 There are several problems for the patient 11 associated with the use of the stents. 12 13 Specifically, these are that during voiding of the bladder, the increased intravesical pressure, which 14 induces evacuation of the bladder, can result in a 15 back flow or reflux of urine. The hollow tube 16 construction allows urine to pass up the stent 17 producing pressure in the kidney as the bladder 18 contracts during urination. These events are known 19 20 as reflux. 21 Urine passing from the kidney to the bladder is 22 If however, the urine becomes contaminated 23 sterile. in the lower urinary tract with infection by 24 pyrogenic organisms, then reflux of this urine may 25 result in the development of sepsis, which can 26 27 damage the kidney and also have potentially lethal 28 consequences for the patient. The risk of sepsis 29 following the employment of an indwelling stent 30 between the kidney and the bladder, means that there 31 is a need to provide a ureteral stent which will maintain an open flow of urine from the kidney to 32

3

the bladder, while also inhibiting the reflux of 1 urine to the kidney. 2 3 Further, during bladder evacuation, the stent may 4 retract into the ureteral orifice. This upwards 5 migration of the stent is seen with many stents of 6 the mono J stent type, wherein the lower end of the 7 stent doesn't have a curl. 8 9 A further problem associated with the use of stents 10 11 is that the lower coil irritates the bladder by touching its lining. This is usually caused by the 12 volume of material comprising the lower coil as well 13 as the tip of the lower coil digging into the 14 15 bladder lining. 16 Presently in the field, there are a number of stents 17 which try to overcome the problems associated with 18 the use of such devices, these are outlined below: 19 20 21 Anti-Reflux Stents 22 An article by Ahmadzadeh (Stenting the Urinary 23 System. D Yachia. ISBN 1899066829) discloses a 24 25 Double Pigtail Stent with a transparent thin walled segment made of polyurethane which is designed to 26 lie at the junction between the ureter and the 27 bladder i.e. at the vesico-ureteric junction. 28 floppy polyurethane walls would co-apt with vesical 29 pressure rise preventing reflux. They would also 30 allow the slit like ureteric orifice, which is a 31 natural valve, to remain closed during intra-vesical 32

1	pressure rises, which is how reflux is prevented in
2	the normal healthy ureter and bladder.
3 :	
4	United States Patent No 5019102 discloses a valve
5	system comprising two thin transparent membranes
6	forming a bag open at the distal end attached to the
7	lower end of an ordinary stent and again as the
8	pressure rises within the bladder these are
9	pressured together preventing reflux of fluid.
10	
11	Conversely when urine needs to be excreted, they
12	open out allowing fluid drainage into the bladder.
13	
14	United States Patent No 564783 teaches of a Double J
15	Stent with a closed lower portion which does not
16	allow urine to drain up or down it and therefore
17	prevents reflux. The lower end also has a small
18	side hole into which the tip of the lower end curls
19	back into after stent placement this being aided by
20	two magnets.
21	
22	Stents to Reduce Bladder Irritation
23	With a Chaban Bahamb No E141502 displaces a group
24	United States Patent No 5141502 discloses a stent with a helical upper end and a lower end made of a
25	softer, non-irritating material but containing a
26	cuff at the level of the vesico-ureteric junction,
27	
28	which allows placement over a guide wire.
29	
30	A stent with a softer coil at the lower end bonded
31	on to reduce bladder irritation is described in US
32	Patent No 4931037.

5

1 International Patent Application No WO 9717094 2 teaches of a stent with a lower portion which tails 3 off into a thinner flexible region whose small diameter reduces bladder irritation and also does 5 not push open the vesico-ureteric junction to such 6 an extent, but which is not hollow so no longer acts 7 as a channel for urine drainage either. 8 9 It is an object of the present invention to provide 10 an improved indwelling ureteric stent to provide 11 12 drainage between the kidney and the bladder. It is a further object of the invention to prevent the 13 reflux of urine from the bladder into the kidney, 14 thereby preventing flank pain associated with 15 16 voiding and also the passage of infected urine in the lower urinary tract into the kidney where this 17 could cause damage to the upper urinary tract. A 18 further aim of the present invention serves to 19 reduce the irritation of the bladder, which is 20 associated with the use of stents. 21 22 According to a first aspect of the present invention 23 there is provided an indwelling ureteral stent 24 constructed of flexible material which comprises a 25 hollow elongated tubular body, said hollow elongated 26 tubular body comprising an upper end section, a 27 substantially straight middle section and a lower 28 end section wherein the tip of the lower end section 29 of the stent comprises a valve which permits the 30 hollow body to be in an open or a closed position 31

6

wherein the valve is an integral part of the 1 2 flexible material comprising the stent. 3 4 More preferably the valve is a bicuspid valve having 5 two leaflets or a tricuspid valve having three 6 leaflets. 7 8 Most preferably the valve is a bicuspid valve. 9 10 In a preferred embodiment the valve is provided through the moulded interlay of the flexible 11 12 material such that in the closed position at rest 13 the leaflets of the valve lie flat against each other providing a seal which prevents urine passing 14 15 up the stent. 16 17 A second aspect of the present invention relates to an indwelling ureteral stent constructed of flexible 18 19 material which comprises a hollow elongated tubular .20 body, said hollow elongated body comprising an upper 21 coiled section, a substantially straight middle 22 section, and a lower end section wherein the lower 23 section forms a closed or substantially closed loop, 24 such that in use the tip of the end section of the 25 stent is not exposed and cannot contact the bladder 26 lining. 27 28 Preferably the stent also comprises a valve as 29 described herein. 30 31 Preferably the lower end section is "G" shaped or 32 spherically shaped such that in use the tip of the

7

end section will not contact the lining of the 1 2 bladder. 3 Preferably the upper section comprises a coil, said 4 5 coil including flexible material between 6 to 15cm 6 of flexible material coiled once or twice upon 7 itself, said coil having a diameter between 1 and 8 2.5cm. 9 Preferably the lower section comprises a coil, said 10 coil including a flexible material wherein said 11 material is coiled thus forming an "O" or a "G" 12 shape with a diameter of between 0.5-2cm and wherein 13 the tip of the stent rests within the coil and 14 therefore, in use does not contact the bladder 15 16 lining. 17 More preferably the lower section is formed into a 18 "G" shape such that the tip of the stent assumes the 19 20 horizontal portion of the G shape. 21 A third aspect of the present invention relates to 22 an indwelling ureteral stent constructed of flexible 23 material which substantially comprises a hollow 24 elongated tubular body, said hollow elongated 25 tubular body comprising an upper end section, a 26 substantially straight middle section and a lower 27 end section wherein the flexible material decreases 28 in external diameter from the upper end section to 29 the lower end section such that there is maximum 30 drainage in the upper urinary tract and minimum 31 32 irritation in the lower urinary tract.

1	
2	Preferably the stent also comprises a valve as
3	described herein the lower end shaped as described
4	herein to prevent contact of the valve in the tip
5	with the bladder lining.
6	
7	More preferably the flexible material is tapered in
8	diameter towards the lower end, such that the lower
9	third of the substantially straight middle section
LO	and the totality of the lower section are of a
L1	reduced diameter.
L2	
L3 ·	A fourth aspect of the present invention relates to
14	an indwelling ureteral stent constructed of flexible
15	material which comprises a hollow elongated tubular
L6	body, said hollow elongated tubular body comprising
L7	an upper end section, a substantially straight
L8	middle section and a lower end section, wherein the
19	stent further comprises at least one projection
20	against which a stent pusher may rest.
21	
22	Preferably the stent also comprises a valve as
23	described herein and / or at least one end of the
24	stent is shaped as described herein to prevent
25	contact of the tip with the bladder lining.
26	
27	Preferably the stent is tapered as described herein.
8	
29	Preferably the projection(s) form a cuff.
30	
31	Preferably the projection(s) consist of a plurality
32	of studs.

T	
2	According to each aspect of the invention the
3	flexible material of the stent may comprise any
4	composition which forms a hollow tube.
5	
6	The flexible material may have a cylindrical cross
7	section.
8	
9	Alternatively the flexible material may have any
10	shape of cross section either throughout it's whole
1	length or in one section alone, such as in the lower
12	third alone, including a spiral, a star or an oval,
L3	especially wherein said shape facilitates drainage
L 4	on the outer surface or accommodation to the natural
15	contours of the urinary tract preventing reflux
L6	around the stent.
١7	•
18	Preferably the flexible material of said stent has
L9	an external diameter in the range 1mm to 5mm.
20	
21	More preferably the flexible material of said stent
22	has as external diameter in the range 1.5mm to 3mm.
23	
24	Preferably the flexible material of said stent is
25	sof flex™, endo sof™ or ultrathane™.
26	
27	The invention is further described with reference to
8	the following figures wherein:
29	
30	Figure 1 illustrates a preferred embodiment of
31	the stent
32	

1	Figure 2 illustrates the G shaped coil
2	
3	Figure 3 illustrates the integral valve
4	
5	Figures 3 and 4 illustrate the projections
6	against which a stent pusher can rest.
7	
8	In one specific embodiment the invention provides a
9	stent which consists of a single piece of flexible
10	material which can be of any suitable composition in
11	that the material forms a hollow tube such as sof
12	$flex^{TM}$, endo sof^{TM} or $ultrathane^{TM}$. This tube is
13	moulded into an upper coil (1) a straight segment
14	(2) and a lower coil (3). Figure 1 is a
15	representation of such a stent. A cross section of
16	the stent is typically cylindrical but may also be
. 17	modified into any shape in cross section either
18	throughout it's whole length or in one section alone
19	such as in the lower third alone (such as a spiral,
20	a star shape or an oval) to facilitate drainage
21	around the outside of the stent or alternatively to
22	aid passage through the urinary anatomy during the
23	placement procedure or allow accommodation to the
24	natural contours of the urinary tract preventing
25	reflux around the stent.
26	
27	The diameter of the cylinder can be of any size but
28	externally would be from about 1.5-3mm (usually
29	1.9mm ie. 6 French gauge) with an internal diameter
30	of about 0.5-2.0mm in the upper coil (1), typically
31	0.9mm. This diameter can be maintained throughout
32	the length of the whole stent.

11

1 2 In a further embodiment of the present invention the 3 diameter of 6 French gauge (1.9mm) may be only 4 maintained for the upper two thirds of the middle segment (2). The diameter then tapers to a diameter 5 of 1.5mm (4.7 French gauge) in the lower third of 6 the middle segment (2) and the lower coil (3). 7 8 In both embodiments of the present invention 9 described above, the upper coil (1) will use about 10 6-15cm of material coiled once or twice upon itself 11 over a diameter of about 1 to 2.5cm. It will allow 12 significant uncoiling during placement to adjust for 13 varying lengths of ureters in different patients. 14 15 The middle segment (2) will generally be about 22cm 16 long, but may be varied to the approximate length of 17 the patients ureter and both it and the upper coil 18 (1) will have small perforations at regular 19 intervals (4) allowing the passage of urine from the 20 outside to the inside of the stent and vice-versa. 21 These perforations will stop in the lower third of 22 the straight segment to avoid reflux in and below 23. 24 this area. 25 The lower coil (3) is made up of about 4 to 5cm of 26 material coiled into a smaller diameter curl of 27 either 1.5cm if it maintains the diameter of a 6 28 French gauge throughout its entirety or 1cm if it 29 tapers to 4.7 French gauge size. This coil will 30 have a G-shape such that the end of the stent forms 31 the horizontal part of the G. Representations of 32

1	such a coil are shown in Figure 2. The G-shape
2	formation of the lower coil prevents the distal tip
3	of the stent touching other parts of the stent and
4	impeding the free action of the valve on this end.
5	It also prevents the end of the stent digging into
6	and irritating the bladder. As mentioned above,
7	this part of the stent is of a smaller diameter
8	(usually 1.5mm ie. 4.7 French gauge) to reduce
9	bladder irritation. The tip of the lower end of the
10	stent is cut and moulded to form a valve (6,7,8),
11	which may be of any kind, but will preferably be of
12	a bicuspid or tricuspid type. Representations
13	illustrating embodiments of the valve as bicuspid
14	and tricuspid types are shown in Figure 3. In a
15	preferred embodiment a bicuspid valve may be
16	provided through moulded interlay of the material
L7	comprising the stent, such that in the resting
18	position the 2 leaflets of the valve lie flat
19	against each other providing a seal which prevents
20	urine passing up the stent.
21	
22	In the stent whose G has diameter of 6 French gauge
23	or 1.9mm in size, the length of the valve will be
24	7mm.
25	
26	In the further embodiment of the present invention
27	in which the diameter tapers down to 4.7 French
28	gauge or 1.5mm in size, the valve itself will be 5mm
29	long.
3.0	

13

The valve leaflets will easily be pushed apart by 1 urine passing down the stent or the guide wire onto 2 which the stent is fed during placement. 3 Located about 3mm behind the valve in both 6 French 5 gauge (1.9mm) and 4.7 French gauge (1.5mm) is a 6 small cuff, or four studs (12) which are again 7 moulded out of the flexible material. This cuff or 8 four studs (12) is used for the stent pusher to rest 9 against when placing the stent over a flexible metal 10 guide wire, this is shown in Figure 4. 11 12 Placement of the stent is facilitated by means of a 13 conventional cystoscope using a conventional guide 14 wire (11) passed through the urethra into the 15 bladder, through the ureteric orifice up the ureter 16 and into the renal pelvis under fluoroscopic 17 The stent is fed onto the guide wire with control. 18 the upper coil first and then pushed into place 19 .20 using a modified conventional stent pusher (10) 21 which fits over the valve and rests against the cuff just behind the valve at the lower curl, thereby 22 23 minimising trauma to the valve on insertion. Once the stent is in place the guide wire and stent 24 pusher are removed. 25 26 Removal of the stent would be through the urethra 27 using a cystoscope or alternatively from above 28 either at the time of surgery on the kidney or with 29 percutaneous retrieval devices. 30 31

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1	1)	Holes in the upper two thirds of the stent
2		allow maximum drainage in and out of the stent
3		to overcome any upper ureteric obstruction.
4		The lack of perforations in the lower third and
5		lower coil prevent reflux.
6	•)•	·
7	2)	The tapering arrangement whereby the tube
8		decreases in external diameter from 1.9mm (6
9	:	French gauge) at the upper diameter to 1.5mm
10		(4.7 French gauge) lower diameter allows
11		maximum drainage in the upper urinary tract and
12		minimum irritation in the lower urinary tract.
13		•
14	3)	The small size of the lower coil causes less
15	;	bladder irritation than conventional stents.
16	•	
17	. 4)	The assumption of a G-shape of the lower coil
18	:	ensures that the end of the stent which is
19		normally free to dig into the bladder does not
20		do this, thereby minimising stent induced
21	;	irritation, which can itself produce unstable
22	•	bladder contractions and secondary reflux of
23	· :	urine.
24	•	
25	5)	The advantage of the herein described valve
26		over existing valves is that the present valve
27	•	is an integral part of the stent rather than
28		being stuck on, therefore there is virtually no
2 9		risk of a piece of the stent falling off or
30		becoming partially detached from the main body
31		of the stent as a retained foreign body. It is
32	:	also much smaller than existing polythene bag

L	valves and should therefore cause less bladder
2	irritation.
3	
4	The present invention can be inserted into patients
5	using a traditional procedure as described above.

•

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1	CLAI	EMS CONTRACTOR OF THE CONTRACT
2	•	
3	1.	An indwelling ureteral stent constructed of
4		flexible material which comprises a hollow
5		elongated tubular body, said hollow elongated
6		tubular body comprising an upper end section,
7		substantially straight middle section and a
8		lower end section wherein the tip of the lower
9		end section of the stent comprises a valve
10		which permits the hollow body to be in an open
11		or a closed position wherein the valve is an
12		integral part of the flexible material
13		comprising the stent.
14	:	
15	2.	An indwelling ureteral stent as claimed in any
16		of the preceding claims wherein the valve is a
17		bicuspid valve having two leaflets or a
18		tricuspid valve having three leaflets.
19		
20	; 3.	An indwelling ureteral stent as claimed in any
21		of the preceding claims wherein the valve is
22		provided through the moulded interlay of the
23		flexible material such that in the closed
24		position the leaflets of the valve lie flat
25		against each other providing a seal which
26		prevents urine passing up the stent.
27		·
28	4.	An indwelling ureteral stent constructed of
29		flexible material which comprises a hollow
30		elongated tubular body, said hollow elongated
31		body comprising an upper section, a
20		substantially straight middle section and a

1		lower end section wherein the upper lower
2		section forms a closed or substantially closed
3		loop, such that in use the tip of the end
4		section of the stent is (are) not exposed and
5	•	cannot contact the bladder lining.
6		•
7	5.	An indwelling ureteral stent as claimed in any
8	·	of the preceding claims wherein the upper and
9		lower end sections form closed or substantially
10 .		closed loops.
11	:	
12	6.	An indwelling ureteral stent as claimed in any
13		of the preceding claims wherein the lower end
14		section is "G" shaped or spherically shaped
15		such that in use the tip of the end section
16		will not contact the bladder lining.
17		
18	7.	An indwelling ureteral stent as claimed in any
19		of the preceding claims wherein the upper
20	•	section comprises a coil, said coil including
21		flexible material between 6 to 15cm coiled once
22		or twice upon itself, said coil having a
23		diameter between 1 and 2.5cm.
24		
25	; 8. -	An indwelling ureteral stent as claimed in any
26		of the preceding claims wherein the lower
27		section comprises a coil, said coil including a
28		flexible material wherein said material is
29		coiled thus forming an "O" or a "G" shape with
30		a diameter of between 0.5-2cm.
31		
3.2	۵	An indwelling preteral stent as claimed in any

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of the preceding claims wherein the lower 1 section is formed into a "G" shape such that 2 the tip of the stent assumes the horizontal 3 portion of the G shape. An indwelling ureteral stent constructed of 6 10. flexible material which substantially comprises 7 a hollow elongated tubular body, said hollow 8 elongated tubular body comprising an upper end 9 section, a substantially straight middle 10 section and a lower end section wherein the 11 flexible material decreases in external 12 diameter from the upper end section to the 13 lower end section such that there is maximum 14 drainage in the upper urinary tract and minimum 15 irritation in the lower urinary tract. 16 17 An indwelling ureteral stent as claimed in any 18 11. of the preceding claims wherein the flexible 19 material decreases in external diameter from 20 the upper end section to the lower end section. 21 22 An indwelling ureteral stent as claimed in any 23 12. of the preceding claims wherein the flexible 24 material is tapered in diameter towards the 25 lower end, such that the lower third of the 26 substantially straight middle section and the 27

18

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30 31

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28 29

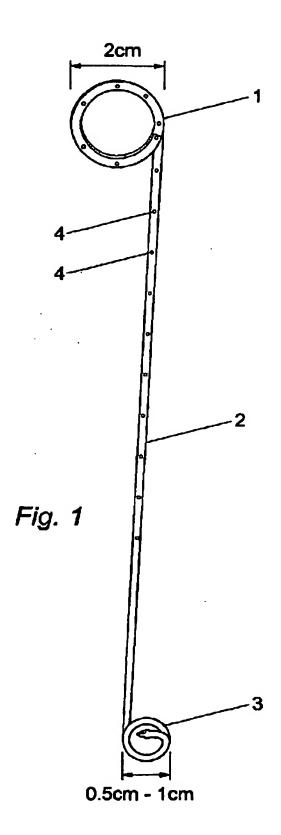
> 13. An indwelling ureteral stent constructed of flexible material which comprises a hollow

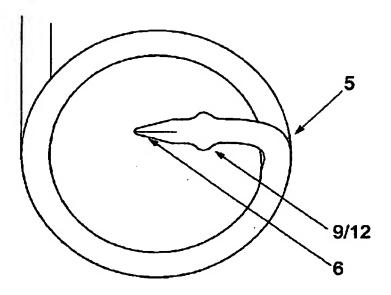
diameter.

totality of the lower section are of a reduced

1		elongated tubular body, said hollow elongated
2		tubular body comprising an upper end section,
3	•	substantially straight middle section and a
4		lower end section, wherein the stent further
5		comprises at least one projection against which
6		a stent pusher may rest.
7		
8	14.	An indwelling ureteral stent as claimed in any
9	*	of the preceding claims wherein the stent
10		further comprises at least one projection
11	•	against which a stent pusher may rest.
12	•	•
13	15.	An indwelling ureteral stent as claimed in
14	:	claims 13 or 14 wherein the projection(s) form
15		a cuff.
16		
17	; 16.	An indwelling ureteral stent as claimed in
18	:	claims 13 to 15 wherein the projection(s)
19		consist of a plurality of studs.
20	:	
21	17.	An indwelling ureteral stent as claimed in any
22		of the preceding claims wherein the flexible
23	:	material includes any composition which forms
24	*	hollow tube.
25		·
26	18.	An indwelling ureteral stent as claimed in any
27		of the preceding claims wherein the flexible
28	:	material has a cylindrical cross section.
29		
30	19.	An indwelling ureteral stent as claimed in any
31	•	of the preceding claims wherein the flexible
32		material has any shape of cross section,
		-

1	·	including a spiral, a star or an oval,
2		especially wherein said shape facilitates
3		drainage on the outer surface.
4		
5	. 20.	An indwelling ureteral stent as claimed in any
6		of the preceding claims wherein the flexible
7		material of said stent has an external diameter
8		in the range 1mm to 5mm.
9	:	
10	21.	An indwelling ureteral stent as claimed in any
11		of the preceding claims wherein the flexible
12	:	material of said stent has an external diameter
13		in the range 1.5mm to 3mm.
14		
15	22.	An indwelling ureteral stent as claimed in any
16		of the preceding claims wherein the flexible
17	•	material is sof flex TM , endo sof TM or
18	:	ultrathane™.





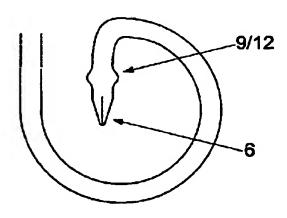
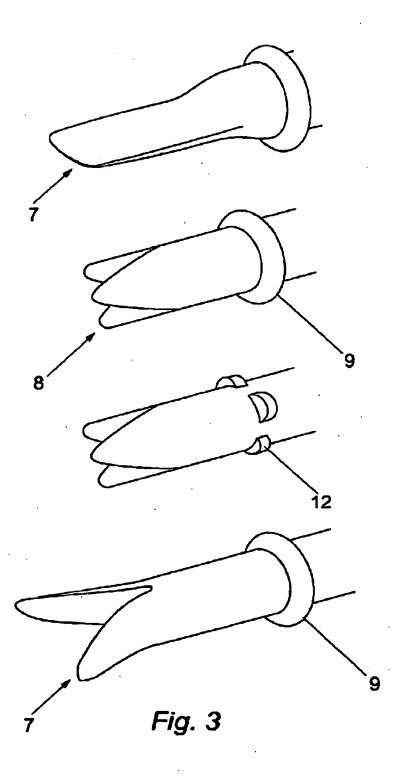
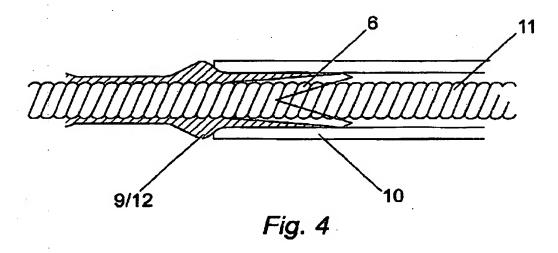


Fig. 2







INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P25453A/RMC	FOR FURTHER see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below	
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)
PCT/GB 01/02323	25/05/2001	26/05/2000
TAYSIDE UNIVERSITY HOSPITA	ALS NHS TRUST et al.	
This International Search Report has been according to Article 18. A copy is being tra	n prepared by this International Searching Auth ansmitted to the International Bureau.	nority and is transmitted to the applicant
	of a total of sheets. a copy of each prior and document cited in this in	report.
language in which it was filed, unle	international search was carried out on the basi ess otherwise indicated under this item.	
the International search wa Authority (Rule 23.1(b)).	as carried out on the basis of a translation of th	ne international application furnished to this
b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing: contained in the international application in written form. filled together with the international application in computer readable form. furnished subsequently to this Authority in written form. the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. the statement that the information recorded in computer readable form is identical to the written sequence listing has been		
3. Unity of invention is lack	nd unsearchable (See Box I). ding (see Box II).	
4. With regard to the title, X the text is approved as sub the text has been establish	omitted by the applicant. ned by this Authority to read as follows:	٠
5. With regard to the abstract, [X] the text is approved as subthe text has been establish within one month from the control of the control	omitted by the applicant. ned, according to Rule 38.2(b), by this Authority date of malling of this international search repo	v as it appears in Box III. The applicant may, ort, submit comments to this Authority.
6. The figure of the drawings to be publis as suggested by the applicate because the applicant failed because this figure better c	eant. od to suggest a figure.	None of the figures.

Form PCT/ISA/210 (first sheet) (July 1998)



Box I Obs rvati ns whire certain claims were found unsearchabl (Continuation if it mit of first sheet)
This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)
This International Searching Authority found multiple inventions in this international application, as follows:
see additional sheet
As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark on Protest The additional search fees were accompanied by the applicant's protest.
No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-3

An indwelling ureteral stent comprising an elongated tubular body, an upper end section, a straight middle section and a lower end section wherein the tip of the lower end section of the stent comprises a valve as an integral part of the flexible material comprising the stent.

2. Claims: 4-9

An indwelling ureteral stent comprising an elongated tubular body, an upper end section, a straight middle section and a lower end section wherein the upper lower section forms a closed loop such that the tip of the end section of the stent is not exposed.

3. Claims: 10-12

An indwelling ureteral stent comprising an elongated tubular body, an upper end section, a straight middle section and a lower end section wherein the flexible material decreases in external diameter from the upper end section to the lower end section.

4. Claims: 13-22

An indwelling ureteral stent comprising an elongated tubular body, an upper end section, a straight middle section and a lower end section wherein the stent further comprises at least one projection against which a stent pusher may rest.

INTERNATIONAL SEARCH REPORT



GB 01/02323

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/04 A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUM	ENTS CONSIDERED TO BE RELEVANT	
Calegory °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Х	WO 99 09911 A (UROSURGE INC) 4 March 1999 (1999-03-04)	1,13,14, 16-19
A	page 9, line 22 -page 10, line 24; figures page 5, line 10 -page 6, line 6	4,5,7,8
X	US 4 225 979 A (REY PIERRE ET AL) 7 October 1980 (1980-10-07) column 3, line 65 -column 6, line 11; figures	1
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Α	US 4 307 723 A (FINNEY ROY P) 29 December 1981 (1981-12-29) column 5, line 34 - line 44; figures	1

X Further documents are listed in the continuation of box C.	Patent family members are listed in annex.
Special categories of cited documents: A' document defining the general state of the art which is not considered to be of particular relevance E' earlier document but published on or after the international filing date L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) O' document referring to an oral disclosure, use, exhibition or other means P' document published prior to the international filing date but later than the priority date claimed	 *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. *&* document member of the same patent family
Date of the actual completion of the international search	Date of mailing of the international search report
25 October 2001	2.9. 11. 2001
Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentiaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Kousouretas, I

INTERNATIONAL SEARCH REPORT

international Application No

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT Category Citation of document, with Indication, where appropriate, of the relevant passages Relevant	
Outchest a programme through the state of th	vant to claim No.
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A column 3, line 60 -column 6, line 3; figures	4,13,14, 16-21
X US 4 931 037 A (WETTERMAN PETER H) 5 June 1990 (1990-06-05)	10,11
A abstract; figures	4,5
A US 5 141 502 A (MACALUSO JR JOSEPH N) 25 August 1992 (1992-08-25) column 3, line 36 - line 51; figures	4,5,10, 11
A US 5 941 823 A (CHAIT PETER G) 24 August 1999 (1999-08-24) abstract; figures	4,5
P,X EP 1 051 989 A (KARBIX ESTABLISHMENT) 15 November 2000 (2000-11-15)	10-12
A the whole document	4,13,14, 17-19

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on on patent family members

International Application No GB 01/02323

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EP 1051989	Α	15-11-2000	EP	1051989 A2	15-11-2000

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PAP NT COOPERATION TREATY

	From the INTERNATIONAL BUREAU					
PCT	То:					
NOTIFICATION OF THE RECORDING OF A CHANGE (PCT Rule 92bis.1 and Administrative Instructions, Section 422) Date of mailing (day/month/year) 30 January 2002 (30.01.02)	MURGITROYD & COMPANY Scotland House 165-169 Scotland Street Glasgow, G5 8PL ROYAUME-UNI					
30 January 2002 (30.01.02)						
Applicant's or agent's file reference P25453A/RMC	IMPORTANT NOTIFICATION					
International application No. PCT/GB01/02323	International filing date (day/month/year) 25 May 2001 (25.05.01)					
The following indications appeared on record concerning: the applicant						
Name and Address MURGITROYD & COMPANY 373 Scotland Street Glasgow G5 80A United Kingdom	State of Nationality Telephone No. 0141 307 8400 Facsimile No. 0141 307 8401 Teleprinter No.					
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning: the person						
Name and Address MURGITROYD & COMPANY Scotland House 165-169 Scotland Street Glasgow, G5 8PL United Kingdom	Telephone No. 0141 307 8400 Facsimile No. 0141 307 8401 Teleprinter No.					
3. Further observations, if necessary: The new address on the demand has been considered as a change of address under Rule 92bis. In case of a disagreement the International Bureau should be notified immediately.						
4. A copy of this notification has been sent to: X the receiving Office the International Searching Authority X the International Preliminary Examining Authority	the designated Offices concerned X the elected Offices concarned other:					
The International Bureau of WIPO 34, chemin des Colombottos 1211 Geneva 20, Switzerland	Authorized officer Sylvaine DESCLOUX					
Facsimile No.: (41-22) 740.14.35 Form PCT/IB/306 (March 1994)	Telephone No.: (41-22) 338.83.38 004628777					

PATENT COOPERATION TREA

To:

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING DOCUMENT TRANSMITTED

Commissioner

US Department of Commerce United States Patent and Trademark

Office, PCT 2011 South Clark Place Room

CP2/5C24

Arlington, VA 22202

ETATS-UNIS D'AMERIQUE

In its capacity as designated Office

International application No. PCT/GB01/02323

Date of mailing (day/month/year)

29 November 2001 (29.11.01)

International filing date (day/month/year) 25 May 2001 (25.05.01)

Applicant

TAYSIDE UNIVERSITY HOSPITALS NHS TRUST et al

The International Bureau transmits herewith the following documents and number thereof:

copy(ies) of declaration(s) (Rule 47.1(a-ter))

The International Bureau of WIPO 34, chemin des Colombettes 1211 Genova 20, Switzerland Authorized officer

м. оисноикні

Telephone No.: (41-22) 338.83.38

Facsimile No.: (41-22) 740.14.35 Form PCT/IB/310 (July 1992)

CENT COOPERATION TREA

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

Commissioner

US Department of Commerce United States Patent and Trademark

Office, PCT

2011 South Clark Place Room

CP2/5C24

Arlington, VA 22202

ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) in its capacity as elected Office 30 January 2002 (30.01.02) Applicant's or agent's file reference International application No. P25453A/RMC PCT/GB01/02323 Priority date (day/month/year) International filing date (day/month/year)

25 May 2001 (25.05.01)

26 May 2000 (26.05.00)

Applicant

RIX, Gerald, Henner

in the demand fill	ed with the International Pre	liminary Examining	Authority on:	
	24 Dece	mber 2001 (24.12	2.01)	
in a notice effecti	ng later election filed with th	ne International Bure	ay on:	
·		· · · · · · · · · · · · · · · · · · ·		
The election X w	8\$			
" "	as not			
made before the expira Rule 32.2(b).	tion of 19 months from the p	priority date or, wher	e Rule 32 applies, withi	the time limit under
:				
:	•			

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

Authorized officer

Sylvaine DESCLOUX

Telephone No.: (41-22) 338.83.38

Form PCT/IB/331 (July 1992)

Facsimile No.: (41-22) 740.14.35

GB0102323

32



REPLACED BY ART 34 AMDT

1	CLAI	ms Pall 34
2		·
3	1.	An indwelling ureteral stent constructed of
4 .		flexible material which comprises a hollow
5		elongated tubular body, said hollow elongated
6		tubular body comprising an upper end section,
7		substantially straight middle section and a
8		lower end section wherein the tip of the lower
9		end section of the stent comprises a valve
10		which permits the hollow body to be in an open
11		or a closed position wherein the valve is an
12		integral part of the flexible material
13		comprising the stent.
14		
15	2.	An indwelling ureteral stent as claimed in any
16		of the preceding claims wherein the valve is a
17		bicuspid valve having two leaflets or a
18		tricuspid valve having three leaflets.
19		·
20	3.	An indwelling ureteral stent as claimed in any
21		of the preceding claims wherein the valve is
22		provided through the moulded interlay of the
23		flexible material such that in the closed
24		position the leaflets of the valve lie flat
25		against each other providing a seal which
26		prevents urine passing up the stent.
27		·
28	4.	An indwelling ureteral stent constructed of
29		flexible material which comprises a hollow
30		elongated tubular body, said hollow elongated
31		body comprising an upper section, a

substantially straight middle section, and a

:		
1		lower end section wherein the upper lower
2		section forms a closed or substantially closed
3		loop, such that in use the tip of the end
4		section of the stent is (are) not exposed and
5	•	cannot contact the bladder lining.
6		·
7	5.	An indwelling ureteral stent as claimed in any
8		of the preceding claims wherein the upper and
9		lower end sections form closed or substantially
10		closed loops.
11		
12	6.	An indwelling ureteral stent as claimed in any
13		of the preceding claims wherein the lower end
14		section is "G" shaped or spherically shaped
15		such that in use the tip of the end section
16		will not contact the bladder lining.
17		
18	7.	An indwelling ureteral stent as claimed in any
19		of the preceding claims wherein the upper
20		section comprises a coil, said coil including
21		flexible material between 6 to 15cm coiled once
22		or twice upon itself, said coil having a
23		diameter between 1 and 2.5cm.
24		
25	8.	An indwelling ureteral stent as claimed in any
26		of the preceding claims wherein the lower
27		section comprises a coil, said coil including a
28		flexible material wherein said material is
29		coiled thus forming an "O" or a "G" shape with
30		a diameter of between 0.5-2cm.
31		
32	9.	An indwelling ureteral stent as claimed in any

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1		of the preceding claims wherein the lower
2		section is formed into a "G" shape such that
3		the tip of the stent assumes the horizontal
4		portion of the G shape.
5		
6	10.	An indwelling ureteral stent constructed of
7		flexible material which substantially comprises
8		a hollow elongated tubular body, said hollow
9		elongated tubular body comprising an upper end
10		section, a substantially straight middle
11		section and a lower end section wherein the
12		flexible material decreases in external
13		diameter from the upper end section to the
14		lower end section such that there is maximum
15		drainage in the upper urinary tract and minimum
16		irritation in the lower urinary tract.
17		
18	11.	An indwelling ureteral stent as claimed in any
19		of the preceding claims wherein the flexible
20		material decreases in external diameter from
21		the upper end section to the lower end section.
22		
23	12.	An indwelling ureteral stent as claimed in any
24		of the preceding claims wherein the flexible
25		material is tapered in diameter towards the
26		lower end, such that the lower third of the
27		substantially straight middle section and the
28		totality of the lower section are of a reduced
29		diameter.
30		
31	13.	An indwelling ureteral stent constructed of
32		flexible material which comprises a hollow

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1		elongated tubular body, said hollow elongated
2		tubular body comprising an upper end section, a
3		substantially straight middle section and a
4		lower end section, wherein the stent further
5		comprises at least one projection against which
6		a stent pusher may rest.
7		
8	14.	An indwelling ureteral stent as claimed in any
9		of the preceding claims wherein the stent
10		further comprises at least one projection
11		against which a stent pusher may rest.
12		•
13	15.	An indwelling ureteral stent as claimed in
14		claims 13 or 14 wherein the projection(s) form
15		a cuff.
16		
17	16.	An indwelling ureteral stent as claimed in
18		claims 13 to 15 wherein the projection(s)
19		consist of a plurality of studs.
20		
21	17.	An indwelling ureteral stent as claimed in any
22		of the preceding claims wherein the flexible
23		material includes any composition which forms a
24		hollow tube.
25		
26	18.	An indwelling ureteral stent as claimed in any
27		of the preceding claims wherein the flexible
28		material has a cylindrical cross section.
29		•
30	19.	An indwelling ureteral stent as claimed in any
31		of the preceding claims wherein the flexible
32		material has any shape of cross section,

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1		including a spiral, a star or an oval,
2		especially wherein said shape facilitates
3		drainage on the outer surface.
4		
5	20.	An indwelling ureteral stent as claimed in any
6		of the preceding claims wherein the flexible
7		material of said stent has an external diameter
8		in the range 1mm to 5mm.
9	•	• •
10	21.	An indwelling ureteral stent as claimed in any
11		of the preceding claims wherein the flexible
12		material of said stent has an external diameter
13		in the range 1.5mm to 3mm.
14		•
15	22.	An indwelling ureteral stent as claimed in any
16		of the preceding claims wherein the flexible
17		material is sof flex TM , endo sof TM or
18		ultrathane™.

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13

The valve leaflets will easily be pushed apart by 1 urine passing down the stent or the guide wire onto 2 which the stent is fed during placement. 3 Located about 3mm behind the valve in both 6 French 5 gauge (1.9mm) and 4.7 French gauge (1.5mm) is a б small cuff, or four studs (12) which are again 7 moulded out of the flexible material. This cuff or 8 four studs (12) is used for the stent pusher to rest 9 against when placing the stent over a flexible metal 10 guide wire, this is shown in Figure 4. 11 12 Placement of the stent is facilitated by means of a 13 conventional cystoscope using a conventional guide 14 wire (11) passed through the urethra into the 15 bladder, through the ureteric orifice up the ureter 16 and into the renal pelvis under fluoroscopic 17 control. The stent is fed onto the guide wire with 18 the upper coil first and then pushed into place 19. using a modified conventional stent pusher (10) 20 which fits over the valve and rests against the cuff 21 just behind the valve at the lower curl, thereby 22 minimising trauma to the valve on insertion. Once 23 the stent is in place the guide wire and stent 24 25 pusher are removed. 26 Removal of the stent would be through the urethra 27 using a cystoscope or alternatively from above 28 either at the time of surgery on the kidney or with 29 percutaneous retrieval devices. 30 31

Gerald Rax

Box No. VIII (iv) DECLARATION: INVENTORSHIP (only for the purposes of the designation of the United States of America)
The declaration must conform to the following standardized wording provided for in Section 214; see Notes to Boxes Nos. VIII, VIII (i) to (v) (in general) and the specific Notes to Box No. VIII (iv). If this Box is not used, this sheet should not be included in the request.

Declaration of inventorship (Rules 4.17(iv) and 51bis.1(a)(iv)) for the purposes of the designation of the United States of America:

I hereby declare that I believe I am the original, first and sole (if only one inventor is listed below) or joint (if more than one inventor is listed below) inventor of the subject matter which is claimed and for which a patent is sought.

This declaration is directed to the international application of which it forms a part (if filing declaration with application).

I hereby declare that my residence, mailing address, and citizenship are as stated next to my name.

I hereby state that I have reviewed and understand the contents of the above-identified into mational application, including the claims of said application. I have identified in the request of said application, in compliance with PCT Rule 4.10, any claim to foreign priority, and I have identified below, under the heading "Prior Applications," by application number, country or Member of the World Trade Organization, day, month and year of filing, any application for a patent or inventor's certificate filed in a country other than the United States of America, including any PCT international application designating at least one country other than the United States of America, having a filing date before that of the application on which foreign priority is claimed.

Prior Applications: British Patent Application No 0012764.7 filed 26 May 2000

and E.B. £ 1.56 including for continuation-it	information that is known by me to be material to patentability as defined by part applications, material information which became available between the filing date nal filing date of the continuation-in-part application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name:	
Residence: United Kingdom (city and either US state, if applicable, or country)	
Mailing Address: 9 MacIntoch Way, Perth, Fill 1SL	
Citizenship: United Kingdom	
Inventor's Signature: (if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent)	Date:
Name: GERALD HENNER RIX	Section 8 (a)
Residence: UNITED WNGDOM (city and either US state, if applicable, or country) Mailing Address: 9 MACKINTOSH WAY PERTH AHI IS	
Citizenship: Inventor's Signature: (if not contained in the request, or if declaration is corrected or added under Rule 261er after the filing of the international application. The signature must be that of the inventor, not that of the agent)	Date: 23rd Ny 2001 (of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)

This declaration is continued on the following sheet, "Continuation of Box No. VIII (iv)".

Form PCT/RO/101 (declaration sheet (iv)) (March 2001)

See Notes to the request form

-PATENT COOPERATION TREATY

GST

From the INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

MURGITROYD & COMPANY Scotland House 165-169 Scotland Street Glasgow G5 8PL GRANDE BRETAGNE PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing (day/month/year)

31.07.2002

Applicant's or agent's file reference

International application No.

P25453A/RMC

PCT/GB01/02323

International filing date (day/month/year)

Priority date (day/month/year)

IMPORTANT NOTIFICATION

25/05/2001 26/05/2000

Applicant

TAYSIDE UNIVERSITY HOSPITALS NHS TRUST et al.

- 1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
- 2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
- 3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (iiling translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

For the purpose of deciding whether the claimed invention is patentable or not, the elected Offices may apply criteria additional to or different from the criteria on which the international preliminary examination report is based (see Articles 27(5), 33(5)). Additional criteria may include e.g. exemptions from patentability and the requirements of enabling disclosure and of clarity and support of claims.

Name and mailing address of the IPEA/

Authorized officer

Ullrich, C

European Patent Office D-80298 Munich

D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d

Fax: +49 89 2399 - 4465

Tel.+49 89 2399-2322



NT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference			FOR FURTHER ACT	HALL	allon of Transmittal of International
P25453A	RMC		, JA FORTHER AU	Prenminary	Examination Report (Form PCT/IPEA/416)
International	applic	ation No.	International filing date (da	y/month/year)	Priority date (day/month/year)
PCT/GB0	1/023	323	25/05/2001		26/05/2000
International A61F2/04		nt Classification (IPC) or na	fonal dassification and IPC		
Applicant					
TAYSIDE	יואט	VERSITY HOSPITAL	S NHS TRUST et al.		
1. This ir and is	terna trans	tional preliminary exami mitted to the applicant a	ination report has been proceeding to Article 36.	repared by this Inte	rnational Preliminary Examining Authority
2. This F	EPO	RT consists of a total of	4 sheets, including this o	cover sheet.	
be	en a	mended and are the bar	d by ANNEXES, i.ė. shee sis for this report and/or s D7 of the Administrative in	heets containing re	n, claims and/or drawings which have ctifications made before this Authority to PCT).
These	anne	exes consist of a total of	5 sheets.		
		·			
		• .			
3. This r	eport	contains indications rela	ating to the following item:	s:	
1	Ø	Basis of the report			
u		Priority	• •		
101		Non-establishment of	pinlon with regard to nov	elty, inventive step	and industrial applicability
IV		Lack of unity of Inventi	on		
. V	Ø		inder Article 35(2) with re- ons suporting such state		entive step or industrial applicability;
VI		Certain documents cit	• • • • • • • • • • • • • • • • • • • •	•	•
VII	_	•	international application		
VIII		Certain observations	on the international applic	ation	
Date of sui	omissi	on of the demand		Date of completion o	f this report
24/12/20	24/12/2001				
Name and	mailin	g address of the Internation	าอเ	Authorized officer	AND LEWIS MINING
prominal)	Eur	opean Patent Office			
) <i>))</i>)		0298 Munich . +49 89 2399 - 0 Tx: 5236	56 epmu d	Hooper, M	
		: +49 89 2399 · 4465	•	Telephone No. +49	89 2399 7438

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY **EXAMINATION REPORT**

International application No. PCT/GB01/02325

l. Bas	is of t	lhe re	port
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1.	Dasi	is of the leb		•
1.	the r	receivina Offi	ice in response to an invitation exed to this report since they do	application (Replacement sheets which have been furnished to under Article 14 are referred to in this report as "originally filed" o not contain amendments (Rules 70.16 and 70.17)):
	1-12	14,15	as originally filed	
	13		with telefax of	14/06/2002
	Clalı	ms, No.:		
	1-21		with telefax of	16/07/2002
	Drav	wings, shee	ts:	
	1/4,3	3/4,4/4	as originally filed	
	2/4	;	with telefax of	14/06/2002
2.	With	regard to th	e language, all the elements in the international application	narked above were available or furnished to this Authority in the was filed, unless otherwise indicated under this item.
	The	se elements	were available or furnished to	this Authority in the following language: , which is:
		the languag	e of a translation furnished for	the purposes of the international search (under Rule 23.1(b)).
		the languag	e of publication of the internati	onal application (under Rule 48.3(b)).
		the languag 55.2 and/or		the purposes of international preliminary examination (under Rule
3.	With	n regard to a mational pre	ny nucleotide and/or amino a diminary examination was carr	acid sequence disclosed in the international application, the led out on the basis of the sequence listing:
			n the international application i	·
		filed togeth	er with the international applica	ation in computer readable form.
		furnished s	ubsequently to this Authority in	written form.
		furnished s	ubsequently to this Authority in	computer readable form.
		The statem	nent that the subsequently furn tional application as filed has b	Ished written sequence listing does not go beyond the disclosure in seen furnished.
		The statem	nent that the information record	led in computer readable form is identical to the written sequence

listing has been furnished.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB01/02323

4.	The	amendments have re	sulted in th	e cancell	llation of:
		the description,	pages:	•	
		the claims,	Nos.:		
		the drawings,	sheets:		
5.		This report has been considered to go bey	established	d as if (so sclosure a	ome of) the amendments had not been made, since they have been as filed (Rule 70.2(c)):
		(Any replacement sh report.)	eet contain	ing such	amendments must be referred to under item 1 and annexed to this .
6.	Add	litional observations, i	f necessan	/ :	
v.	Rea	asoned statement un itions and explanation	der Article ons suppo	e 35(2) wi	rith regard to novelty, inventive step or industrial applicability; ch statement
1.	Sta	tement			·
	Nov	relty (N)	Yes: No:	Claims Claims	
	inve	entive step (IS)	Yes: No:	Claims Claims	
	Ind	ustrial applicability (IA	Yes: No:	Claims Claims	
2.		ations and explanations separate sheet	ns		

Re Item V

1. Reference is made to the following document.

D1: EP-A-0 208 841

 Document D1, which is considered to represent the closest prior art, shows (see D1, figure 1) a stent with the features of the preamble of claim 1.

The difference between the subject-matter of claim 1 and the device of D1 is the provision of an integral valve in the tip of the lower end section. The subject-matter of claim 1 is therefore new, Article 33(2) PCT.

3. The technical problem to be solved can be regarded as providing a stent with a more reliable construction which additionally prevents reflux. This problem is solved by the provision of an integral valve. Such an integral valve is not liable to separate from the remainder of the stent during use, which might happen with valves that are subsequently attached to the device.

None of the documents cited in the search report show such an integral valve, nor is it an obvious workshop modification for the person skilled in the art. The subject-matter of claim 1 therefore comprises an inventive step, Article 33(3) PCT, in view of the available prior art.

4. Claims 2-21 are all directly or indirectly dependent on claim 1 and are therefore also considered to be novel and inventive.

Further points to note

The description is not in conformity with the amended claims, Rule 5.1(a)(iii) PCT.

The valve leaflets will easily be pushed apart by 1. urine passing down the stent or the guide wire onto 2 which the stent is fed during placement. 3 4 Located about 3mm behind the valve in both 6 French 5 gauge (1.9mm) and 4.7 French gauge (1.5mm) is a б small cuff, or four studs (12) which are again 7 moulded out of the flexible material. This cuff (9) 8 or four studs (12) is used for the stent pusher to 9 rest against when placing the stent over a flexible 10 metal guide wire, this is shown in Figure 4. 11 12 Placement of the stent is facilitated by means of a 13 conventional cystoscope using a conventional guide 14 wire (11) passed through the urethra into the 15 bladder, through the ureteric orifice up the ureter 16 and into the renal pelvis under fluoroscopic 17 control. The stent is fed onto the guide wire with 18 the upper coil first and then pushed into place 19 using a modified conventional stent pusher (10) 20 which fits over the valve and rests against the cuff 21 just behind the valve at the lower curl, thereby 22 minimising trauma to the valve on insertion. Once 23 the stent is in place the guide wire and stent 24 pusher are removed. 25 26 Removal of the stent would be through the urethra 27 using a cystoscope or alternatively from above 28 either at the time of surgery on the kidney or with 29 percutaneous retrieval devices. 30

1.	CLA	ims .
2		
3	1.	An indwelling ureteral stent constructed of a
4		flexible material including a hollow elongated
5		tubular body, the hollow elongated tubular body
6		comprising an upper end section (1), a
7	,	substantially straight middle section (2) and a
8		lower end section (3) characterised in that the
9	_	tip of the lower end section forms an integral
.0	. `	valve (6).
11		
.2	2.	An indwelling ureteral stent as claimed in
L3 ·		claim 1, wherein the lower section forms a
4	٠.	closed or substantially closed loop, such that
.5		in use the tip of the lower end section (3) of
16		the stent does not contact the bladder lining.
L7 _		
.8	3.	An indwelling ureteral stent as claimed in
19 .		claims 1 or 2, wherein the lower end section
0 2		(3) is "G" shaped.
21		+
22	4.	An indwelling ureteral stent as claimed in any
23		preceding claim wherein the lower section is
24.	•	formed into a "G" shape and where the tip of
25		the stent assumes the horizontal portion of the
26	•	G shape.
27		
8 5	5.	An indwelling ureteral stent as claimed in
29		claim 2, wherein the lower end section (3) is
30		spherical in shape.

31

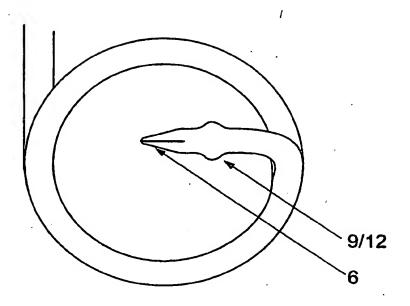
32

6. An indwelling ureteral stent as claimed in any

1		of the preceding claims wherein the lower end
2		section (3) has a diameter of between 0.5 to
3		2cm.
4		
5	7.	An indwelling ureteral stent as claimed in any
6		of the preceding claims wherein the upper
7		section (1) comprises a coil, the coil being
8	, •	formed of between 6 to 15cm of material coiled
9		once or twice upon itself, the coil having a
.0		resulting diameter of between 1 to 2.5cm.
.1		•
.2	8.	An indwelling ureteral stent as claimed in
.3		claims 1 to 7, wherein the valve is a bicuspid
4		valve having two leaflets (7) or a tricuspid
.5		valve having three leaflets (8).
.6		
7	9	An indwelling ureteral stent as claimed in
.8	•	claims 1 to 8, wherein the valve is provided
٠ وا		through the moulded interlay of the flexible
0.0		material such that in the closed position the
21		leaflets of the valve lie flat against each
22 ·		other providing a seal which prevents fluid
23		passing into the stent.
24		
25	10.	An indwelling ureteral stent as claimed in any
26	•	preceding claim wherein the flexible material
27		decreases in external diameter from the upper
28	•	end section (1) to the lower end section (3).
29		
30	11.	An indwelling ureteral stent as claimed in
31		claim 10, wherein the flexible material is
32		tapered from the upper end section (1) to the

1		lower end section (3), such that the lower
2		third of the middle section (2) and the
3		totality of the lower section (3) are of a
4		reduced diameter to that of the upper end
5		section (1).
6		
7	. 12.	An indwelling ureteral stent as claimed in any
g.		preceding claim wherein the stent further
. 9		comprises at least one projection (12) against
10		which a stent pusher may rest.
11	•	
12	13.	An indwelling ureteral stent as claimed in
1.3	0	claim 12 wherein the at least one projection
L 4		forms a cuff (9).
. 5		
L6	14.	An indwelling ureteral stent as claimed in
17	•	claim 12 wherein the at least one projection
L8 ,	٠.	consist of a plurality of studs.
Ľ9		
20	15.	An indwelling ureteral stent as claimed in any
21	:	preceding claim wherein the stent is
22		constructed of a flexible material.
23		
24	16.	An indwelling ureteral stent as claimed in
25		claim 15, wherein the flexible material
26	•	includes any composition which forms a hollow
27		tube.
28		·
29	17.	An indwelling ureteral stent as claimed in
3 oʻ	:	claim 15 wherein the flexible material has a
31		cylindrical cross section.
32		

1	18.	An indwelling ureteral stent as claimed in
-2	•	claim 15 wherein the flexible material has a
3		spiral, star or oval shaped cross section.
4		
5	19.	An indwelling ureteral stent as claimed in any
6.		of claims 15 to 18 wherein the flexible
7 .		material of said stent has an external diameter
8		in the range 1mm to 5mm.
9	:	
10	20.	An indwelling ureteral stent as claimed in any
11	•	of claims 15 to 18 wherein the flexible
12		material of said stent has an external diameter
13	٠.	of between 1.5mm to 3mm.
14	,	
15	21.	An indwelling ureteral stent as claimed in any
16		of claims 15 to 20 wherein the flexible
17	•	material is sof flex TM , endo sof TM or



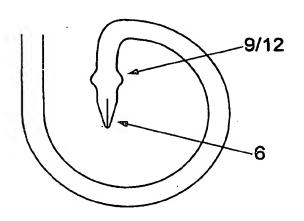


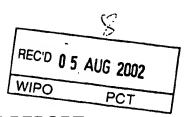
Fig. 2

Quen

Applicant's or agent's file reference

TENT COOPERATION TRE





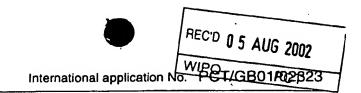
See Notification of Transmittal of International

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

PCT/GB01/02323 25/05/2001 26/05/2000 International Patent Classification (IPC) or national classification and IPC A61F2/04 Applicant TAYSIDE UNIVERSITY HOSPITALS NHS TRUST et al. 1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of 4 sheets, including this cover sheet. Ø This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of 5 sheets. 3. This report contains indications relating to the following Items:	P25453A/RMC			FOR FURTHER AC	HON	Preliminary	Examination Report (Form PCT/IPEA/416)		
International Patent Classification (IPC) or national classification and IPC A61F2/04 Applicant TAYSIDE UNIVERSITY HOSPITALS NHS TRUST et al. 1. This international preliminary examination report has been prepared by this international Preliminary Examining Authority and is transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of 4 sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of 5 sheets. 3. This report contains indications relating to the following items: 1. 3. Basis of the report 1. 9 Priority 1. 10 Non-establishment of opinion with regard to novelty, inventive step and industrial applicability 1. V Lack of unity of invention 2. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement 2. V Certain documents cited 2. V Certain observations on the international application 3. This report contains indications on the international application 3. This report contains indications on the international application 2. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement 2. V Certain observations on the international application 2. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement 2. V Certain observations on the international application 3. The report Certain observations of the international application 2. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citat	International application No.			International filing date (d	ay/month/y	rear)	Priority date (day/month/year)		
Applicant TAYSIDE UNIVERSITY HOSPITALS NHS TRUST et al. 1. This international preliminary examination report has been prepared by this international Preliminary Examining Authority and is transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of 4 sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of 5 sheets. 3. This report contains indications relating to the following items:	PCT/GB0	1/02	323	25/05/2001			26/05/2000		
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II				ting to the following iten	ns:				
III	·		•						
IV				pinion with regard to no	velty, inve	entive step	and industrial applicability		
citations and explanations suporting such statement VI	IV								
VII Certain defects in the international application Certain observations on the international application Date of submission of the demand Date of completion of this report 31.07.2002 Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 · 0 Tx: 523656 epmu d Fax: +49 89 2399 · 4465 Telephone No. +49 89 2399 7438	V	×	Reasoned statement un citations and explanation	nder Article 35(2) with re ons suporting such state	gard to n ment	ovelty, inv	entive step or industrial applicability;		
Date of submission of the demand Date of submission of the demand 24/12/2001 Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 Date of completion of this report 31.07.2002 Authorized officer Hooper, M Telephone No. +49 89 2399 7438	VI		*						
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT



I. Bas	is of	the r	eport
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1.	the and	receiving Office in l	ation (Replacement sheets which have been furnished to Article 14 are referred to in this report as "originally filed" intain amendments (Rules 70.16 and 70.17)):				
	1-12	2,14,15	as originally filed				
	13		with telefax of	14/06/2002			
•	Ctai	ms, No.:					
	1-21		with telefax of	16/07/2002			
	Dra	wings, sheets:					
	1/4,	3/4,4/4	as originally filed				
	2/4	:	with telefax of	14/06/2002			
		Ÿ					
2.	With	n regard to the language in which the	guage, all the elements marked intemational application was file	above were available or furnished to this Authority in the d, unless otherwise indicated under this item.			
	The	se elements were	available or furnished to this Aut	hority in the following language: , which is:			
		- · ·		poses of the international search (under Rule 23.1(b)).			
		the language of a 55.2 and/or 55.3).		poses of international preliminary examination (under Rule			
3.	With	n regard to any nuo rnational prelimina	cleotide and/or amino acid sec ry examination was carried out c	uence disclosed in the international application, the on the basis of the sequence listing:			
		☐ contained in the international application in written form.					
		filed together with the international application in computer readable form.					
		furnished subsequently to this Authority in written form.					
		furnished subsequently to this Authority in computer readable form.					
		The statement that the international a	at the subsequently furnished wr application as filed has been furn	itten sequence listing does not go beyond the disclosure in ished.			
	☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.						

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB01/02323

4. The amendments have resulted in the cancellation of:				llation of:	
		the description,	pages:		•
		the claims,	Nos.:		
		the drawings,	sheets:		
5.					ome of) the amendments had not been made, since they have bee as filed (Rule 70.2(c)):
		(Any replacement sh report.)	eet contair	ning such	n amendments must be referred to under item 1 and annexed to this
6.	Add	litional observations, i	f necessar	y:	
V.		soned statement un itions and explanation			vith regard to novelty, inventive step or industrial applicability; ch statement
1.	Sta	tement			•
	Nov	veity (N)	Yes: No:	Claims Claims	1-21
	Inve	entive step (IS)	Yes: No:	Claims Claims	1-21
	Indi	ustrial applicability (IA) Yes: No:	Claims Claims	1-21
					•



INTERNATIONAL PRELIMINARY **EXAMINATION REPORT - SEPARATE SHEET**

R Item V

Reference is made to the following document.

D1: EP-A-0 208 841

2. Document D1, which is considered to represent the closest prior art, shows (see D1, figure 1) a stent with the features of the preamble of claim 1.

The difference between the subject-matter of claim 1 and the device of D1 is the provision of an integral valve in the tip of the lower end section. The subjectmatter of claim 1 is therefore new, Article 33(2) PCT.

The technical problem to be solved can be regarded as providing a stent with a 3. more reliable construction which additionally prevents reflux. This problem is solved by the provision of an integral valve. Such an integral valve is not liable to separate from the remainder of the stent during use, which might happen with valves that are subsequently attached to the device.

None of the documents cited in the search report show such an integral valve, nor is it an obvious workshop modification for the person skilled in the art. The subject-matter of claim 1 therefore comprises an inventive step, Article 33(3) PCT, in view of the available prior art.

Claims 2-21 are all directly or indirectly dependent on claim 1 and are therefore 4. also considered to be novel and inventive.

Further points to note

The description is not in conformity with the amended claims, Rule 5.1(a)(iii) PCT.